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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/479,783	01/07/2000	STANLEY T CROOKE	ISIS-4313	3541

7590

05/01/2003

Gwilm J. O. Attwell
1900 Market Street
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EXAMINER

MCGARRY, SEAN

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 05/01/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Application No.

09/479,783

Applicant(s)

CROOKE, STANLEY T

Office Action Summary

Examiner

Sean R McGarry

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-46, 68-82 and 89-105 is/are pending in the application.
- 4a) Of the above claim(s) 43-46, 68-77, 89-92 and 103-105 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 78-81 and 93-105 is/are rejected.
- 7) ☒ Claim(s) 93 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 10 February 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 6, 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Applicant's election with traverse of Group II, claims 78-81 and 93-102 in Paper No. 13, filed 10/29/02 is acknowledged. The traversal is on the ground(s) that it would not be a serious burden to combine several of the groups together. This is not found persuasive because the search and considerations required for the different groups are no coextensive as is evidenced by their separate classifications and known divergence in the art as was set forth in the restriction requirement mailed 10/01/02.

The requirement is still deemed proper and is therefore made FINAL.

Claims 43-46, 68-77, 89-92, and 103-105 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 78-81, and 94-102 rejected under 35 U.S.C. 102(b) as being anticipated by Agrawal et al [WO 94/01550].

The instantly claimed invention is based on the observed target substrate for a dsRNase from T24 cells. The claimed invention is a double stranded RNA that

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comprises a first RNA having at least four consecutive ribofuranosyl residues having phosphodiester bonds and either of the oligonucleotides having modifications that allow increases nuclease resistance of increased substrate affinity including 2'methoxy modifications. The invention also reads on a double stranded RNA where both RNA oligonucleotide contain at least four consecutive ribofuranosyl residues. Further limitation includes that at least one of the oligonucleotides comprise from eight to fifty nucleoside units or comprise from 12 to 30nucleoside subunits.

Agrawal et al have disclosed double stranded RNA duplexes. It has been disclosed that the double stranded RNAs comprise a targeting sequence and a self-complementary sequence (see page 8, for example). It has been disclosed at page 15, for example, that the self-complementary region can comprise 4 or more or 10 consecutive base pairing moieties and will generally be less than 50. It is disclosed at page 15, for example, that the regions can be connected by a non-nucleotide linker (i.e. 2 distinct oligonucleotide segments joined by a non-nucleotide linker). At page 16 it is disclosed that the self-complementary region can contain ribonucleotides and further one page 16 it has been disclosed the use of modifications such as 2'-o-Me ribonucleotides to hyperstabilize. It is also disclosed intercalating moieties (which clearly increase affinity between two complemntary nucleic acids) at page 17, for example. at page 19 it has been disclosed both modifications for increasing nuclease resistance and for increased duplex stability. It has further been taught that the two oligonucleotides can be a target RNA sequence and a ribozyme (see page 20 and Figure 7). See also

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figure 6. Agrawal et al have therefore disclosed all the limitations of the instantly claimed invention.

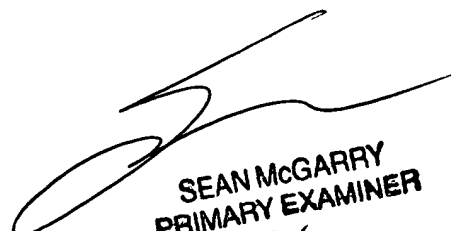
Claim 93 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach a duplex RNA comprising SEQ ID NO: 8.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SRM
April 30, 2003



SEAN MCGARRY
PRIMARY EXAMINER
(635)